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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|------------------------|-------------------------|------------------|
| 09/973,568 | 10/09/2001 | Haralambos Mantzaridis | 2425-18 | 7343 |
| 23117 | 7590 05/21/2003 | | | |
| NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR | | | EXAMINER | |
| | | | FOREMAN, JONATHAN M | |
| ARLINGTON, VA 22201-4714 | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |
| | | | DATE MAILED: 05/21/2003 | 14 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | Ø (| | | |
|---|-----------------------|---|--------------------|--|--|--|
| | Application No. | Applicant(s | Applicant(s) | | | |
| | 09/973,568 | MANTZARIC | MANTZARIDIS ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Jonathan ML Fore | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | |
| 1) Responsive to communication(s) filed on | · | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ T | his action is non-fir | al. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-4 and 7-18</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-4 and 7-18</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/ | or election requiren | nent | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ⊠ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) | Interview Summary (PTO-413) Pa Notice of Informal Patent Applicati Other: | | | | |

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DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: it appears that applicant has unintentionally used the phrase "the signal AEP" in line 7 as opposed to "the AEP signal".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1 4, 7, 9 and 11 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over John '467 in view of Webb et al., and further in view of De Beer et al. John '467 teaches a method and system for calculating an index indicative of anesthetic depth of a patient as claimed by applicant including subjecting the patient to a repetitive audio stimulus, monitoring evoked electrical signals via an EEG produced by the patient in response to the auditory stimulus, providing a signal of the coarseness of the signals and using the signals as an index indicative of the anesthetic depth.

 However, John'467 does not point out that the auditory evoked potentials (AEP) are what is monitored. Nor does John '467 show the coarseness of the signal being a measure increasing with amplitude and frequency of variations in the AEP signal. Webb et al. teaches that AEP can be monitored in EEG signals. De Beer et al. teaches that amplitude and frequency of AEP signals increase in anesthetized patients which are responsive to surgical procedures; that AEP amplitudes are sensitive to pain stimuli (See "Response to Sternotomy" and "Effect of Pain on the AEP and

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EEG", Page 691). It would have been obvious to one having ordinary skill in the art at the time the invention was made to monitor the AEP signals of the patient form the EEG signals as taught by Webb et al., and to modify the coarseness as disclosed by John' 467 to include a measure increasing with amplitude and frequency of variations in the AEP signal as taught by De Beer et al. in order to monitor the depth of anesthesia of the patient in that AEP signals are more suitable to predict inadequate anesthesia than EEG features (De Beer et al., "Prediction of a Response to Incision", Page 692). It would have been an obvious engineering design choice to monitor the AEP signals in sweeps or frames and to manipulate the data as desired to obtain the best readings of the AEP to determine anesthetic depth of the patient, i.e. time averaging the sweeps and producing digitized AEP signals.

3. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over John '467 in view of Webb et al., and further in view of De Beer et al as applied to the claims above, and still further in view of Cosgrove et al. John '467, Webb et al. and De Beer are discussed above.

However, John '467 in view of Webb et al. and further in view of De Beer does not disclose using the signal corresponding to the coarseness to regulate the anesthetic supply. Cosgrove et al. teach a closed loop control of supplying a dosage to a patient by a feedback signal. It would have been obvious, in view of Cosgrove et al., to use the signal corresponding to the coarseness as a feedback signal to automatically control the supply of the dosage of anesthesia to the patient to keep the patient at a desired anesthetic depth.

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

JMLF

May 15, 2003.

MAX F. HINDENBURG SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700